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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,696	09/19/2003	Ulrich Feige	A-527H	8548

7590 09/29/2005

US Patent Operations/[TJG]
Dept. 4300, M/S 27-4-A
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Thousand Oaks, CA 91320-1799

EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,696

Applicant(s)

FEIGE ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/2005 has been entered.

Status of Claims

Claims 1-7 and 63-64 are pending in the application and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

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at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action (5/4/2005).

Response to Arguments

Applicants state that the statement made by the examiner in the Advisory action and other Office actions suggest that the presence of the "randomized Ang-2 binding peptide" is objectionable under section 112, first paragraph.

The Applicants wish to call the examiner's attention to U.S. Pat. App. 2003/0236193, published December 25, 2003, and the references cited therein. The references cited in this published application show that ang-2 was known prior to the applicants' filing date. Moreover, the specification of the published application shows actual preparation and characterization of ang-2 binding peptides and peptibodies using the methods described in the subject application.

In response, the randomized Ang-2 binding peptides have been rejected under this statute because it is not described in the specification as of the filing date. It thus raises the question whether applicants are in possession of the claimed randomized Ang-2 binding peptide. at the time of the filing. The references cited in USA 2003/0236193 ('193 Patent) do not disclose a randomized Ang-2 binding peptide. (Applicants failed

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to specifically point out which references are relied upon.)

More importantly, the claimed composition comprising a randomized Ang-2 binding peptide, which applicants assert is novel. Furthermore, it is not clear just what exactly the methods described in the instant application has been employed by the '193 patent as the instant application does not describe a randomized Ang-2 binding peptide. Except for the general statements made in the instant specification regarding Ang-2 binding peptide, there is no complete disclosure as to this randomized Ang-2 binding peptide i.e., peptide that are modified in every conceivable manner. The disclosure, at the time of filing, describes compounds that are remotely structurally related to randomized Ang-2 Binding peptide.

Applicants further call the examiner's attention to U.S. Pat. Nos. 6,743,788, 6,660,843, 6,872,393, 6,824,782, 6,596,757, 6,706,708, and 6,310,039. The .788 and '843 Patents that claim molecules of similar structure to the Applicants' claims but with different binding specificity. In the '393 and '782 patents, the claims are directed toward molecules having a "peptide linker" of undefined sequence that links antibody heavy or light chains that are not defined by sequence or binding specificity. The '757 and '708 patents claim molecules linking a "taxane" to a "cell binding agent" (claim 20

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of the '757 patent, claim 4 of the '708 patent). The aforementioned patents include claims defining an invention with both structural and functional parameters, frequently with one substituent defined structurally and another defined functionally. These patents use broader structural or functional parameters--or both- than are employed by the Applicants' current claims. Here, the Applicants define part of the overall molecule structurally (Fc domain) and another part by a combination of functional language (ang-2 binding) and structural language (peptides of 2 to 40 amino acids). The Applicants fail to see how their ang-2 binding peptides could render the claims objectionable under Section 112, first paragraph in view of the aforementioned patented molecules, which comprise substituents defined only as "cell binding agent," "cytostatic compound," "peptide linker," and the like. In reply, each case is treated on its own merits. Furthermore, each of the patents e.g., '788 provides a description of the claimed invention. A claim to a randomized Ang-2 binding peptide should describe said randomized Ang-2 binding peptide and not other targets to which a peptide binds thereto. The law is clear in its requirement that at the time the application was filed, applicants had possession of the claimed invention. Thus, reference to other numerous examples of peptides except that,

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which is claimed, is not a description of the claimed randomized Ang-2 binding peptide. As applicants acknowledged above applicants define part of the overall molecule i.e., the known Fc molecule. However, it appears that the novelty of the instant invention resides on the random binding peptide that binds to ang-2. The structural language peptides of 2-40 amino acids is simply a language with no structure for even a single e.g., dipeptide. This dipeptide could read on an innumerable numbers of amino acids, natural or synthetic, singly or in combinations.

Claim Rejections - 35 USC § 103

Claims 1-7 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerretti et al (WO 00/75323) for reasons set forth in the last Office action (5/2/2005).

Since applicants have not addressed this rejection, it is believed that applicants are acquiescing therewith. (Note that the Advisory action only presents rebuttal to the 112 rejection, but has not withdrawn this rejection.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 63-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Oliner et al (USA 20030236193).

Oliner describes at paragraph [0027] a composition comprising Fc and of a random peptides that bind to Ang-2 comprising the sequence or formula as recited therein. In another embodiment, the invention relates to a polypeptide capable of binding Ang-2 comprising an amino acid sequence of the formula: a1-a2-a3-Ca -5WDPWTC-a12-a13-a14 (SEQ ID NO: 69) wherein each of the amino acids are defined at paragraphs [0028]-[0041]. In paragraph [0070] the composition is specifically described. Accordingly, the specific composition of Oliner describing the specific amino acids in the peptide sequence of the composition anticipates the broad claimed composition. [Note applicants are not entitled to the priority date of 10/23/1998 since the provisional application does not describe randomized Ang-2 binding peptide. Neither does the present application having a filing date of 9/19/2003.]

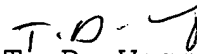
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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw

September 23, 2005